IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT CARDIOVASCULAR SYSTEMS INC. and ABBOTT LABORATORIES INC., Plaintiffs, v. MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC., Defendants.	C. A. No. 98-80 (SLR) (Consolidated with C.A. No. 98-314 (SLR) and C.A. No. 98-316 (SLR)) **REDACTED -- PUBLIC VERSION**

ABBOTT'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO LIFT STAY OF PROCEEDINGS ON ABBOTT'S MOTION FOR PERMANENT INJUNCTION AS TO MEDTRONIC'S ENDEAVOR

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Dated: April 3, 2008

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I. INTRODUCTION

On August 6, 2007, this Court stayed Abbott's motion for a permanent injunction with respect to Medtronic's drug-coated Driver stent—the "Endeavor"—so that the parties could arbitrate Medtronic's claim that it had a license to sell the Endeavor under Abbott's patents-in-suit. In early February 2008, before completion of the arbitration, Medtronic launched the Endeavor in the United States. Last month, the arbitrator, [redacted] ruled against Medtronic on all issues, [redacted] Now that Medtronic has lost the arbitration, the stay should be lifted and an injunction should issue.

Although Medtronic concedes that the Endeavor is simply the Driver stent with a drug coating on it, Medtronic nonetheless has requested that the Court require Abbott to file a separate lawsuit against the Endeavor, which would further delay Abbott's ability to redress Medtronic's infringement and needlessly waste judicial resources. Because the Endeavor's platform is the infringing Driver stent, however, this Court *already* has adjudicated Medtronic's Endeavor as an infringing product by virtue of its judgment that the Driver stent infringes. Specifically, each sale of the Endeavor simultaneously constitutes a sale of Medtronic's infringing Driver stent. Accordingly, the Court should grant Abbott's motion to lift the stay on injunction proceedings for the Endeavor and issue an injunction to stop Medtronic's infringement.

If the Court grants Abbott's motion to lift the stay, Medtronic alternately requests that the Court delay the injunction proceedings for up to *nine* months to permit Medtronic to take extensive discovery on its Endeavor. Medtronic, however, fails to identify any discovery concerning its own product that it could possibly obtain from Abbott that is not already within Medtronic's possession or in the public domain. Medtronic's request for nine months of

discovery on its own product is an improper attempt to further delay the injunction proceedings and should be denied

II. ARGUMENT

A. The Court Should Enter an Injunction That Precludes Medtronic From Making and Selling Its Endeavor

1. The Endeavor Already Has Been Adjudicated as an Infringing Product Because Its Platform Is the Infringing Driver Stent

While Medtronic alleges that the Endeavor has "never been a part of this 10-year litigation" (D.I. 828 at 5 (emphasis omitted)) and that the Endeavor "has not been adjudicated" (*id* at 6), that simply is not true. It is undisputed that the stent platform for the Endeavor is Medtronic's Driver stent, which has been found to infringe Abbott's patents-in-suit, both by a jury (in February 2005) and by this Court (in May 2007). Indeed, Medtronic has touted this fact to the public, stating that the "Endeavor drug-eluting stent ... is built on the same platform as the popular Medtronic Driver® bare metal stent ... ." (Ex. 1[1] [Medtronic News Release dated Oct. 4, 2006]; *see also* Ex. 2 ("The Medtronic Endeavor Drug Eluting Coronary Stent system combines Medtronic's Driver Coronary Stent, the drug ABT-578 and a PC polymer into a drug eluting stent system designed to reduce restenosis") [Medtronic News Release dated May 26, 2004].) The Court likewise has observed that "the 'Endeavor' stent is a drug-eluting stent that uses as its platform one of the devices found to be infringing at bar." (D.I. 756.) Accordingly, each sale of the Endeavor also involves the sale of Medtronic's infringing Driver stent.

[1] References to "Ex. __ at __" refer to exhibits attached to the affidavit of Anne Shea Gaza, filed concurrently herewith.

Therefore, the Endeavor has been adjudicated by virtue of the Court's judgment that the Driver stent infringes Abbott's patents-in-suit.[2] (D.I. 715, 719)

2. Abbott Does Not Need to Bring a Separate Action to Address Medtronic's Infringing Sales of Its Drug-Coated Driver Stent

Even though Medtronic's Endeavor is a drug-coated Driver stent, Medtronic argues that "the Court should require Abbott to bring a new action naming Endeavor as an accused device before it may seek relief against Endeavor." (D.I. 828 at 7.) Medtronic also argues—without citing *any* support—that it is "contrary to the law" for the Court to issue an injunction against Medtronic's Endeavor. (*Id.* at 6.) Medtronic's arguments, however, are incorrect and amount to nothing more than an improper attempt to waste judicial resources and to avoid the Court's judgment. As explained above, because the Endeavor's platform is the infringing Driver stent, the Endeavor already has been adjudicated as infringing each of the patent claims that the Driver stent infringes (*i.e.*, claims 5 and 8 of U.S. Patent No. 6,066,167; claims 1, 3, and 11 of U.S. Patent No. 6,066,168; and claims 1-3 and 9 of U.S. Patent No. 6,432,133).

Moreover, Medtronic cannot avoid the Court's judgment that the Driver stent infringes merely by adding a drug coating to the stent. As explained in *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044 (Fed. Cir. 1988), "[a]dding features to an accused device will not result in noninfringement if all the limitations in the claims or equivalents thereof, are present in the accused device." *Id.* at 1057-58; *see also Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 945 (Fed. Cir. 1990) ("The addition of features does not avoid infringement, if all the

[2] Medtronic's argument that the Endeavor should be litigated under the current law is moot inasmuch as the Endeavor—which is a drug-coated Driver stent—already has been adjudicated as an infringing product. While Abbott disagrees with Medtronic's contention that the Supreme Court's decision in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007) affects the Court's judgment in this case, Medtronic will have an opportunity to challenge any of the Court's legal rulings on appeal (to the extent it has preserved the issue).

elements of the patent claims have been adopted"); *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 703 (Fed. Cir. 1983) ("[A] pencil structurally infringing a patent claim would not become noninfringing when incorporated into a complex machine that limits or controls what the pencil can write"). Accordingly, Medtronic's addition of a drug coating to its infringing Driver stent does not transform that stent into a noninfringing product.

3. Abbott Has Presented Evidence Establishing That an Injunction Covering the Endeavor Should Issue

In Abbott's Opening Brief in Support of Its Motion for Permanent Injunction, Abbott presented evidence that it would suffer significant additional irreparable harm if Medtronic were permitted to release its Endeavor into the U.S. market. (D.I. 727 at 17-18.) Abbott also showed that the public interest and the balance of hardships favor entry of an injunction that would prevent sales of Medtronic's infringing Endeavor. (*Id.* at 22-26.) Now that Medtronic has released its Endeavor into the U.S. market, Abbott, in fact, has suffered substantial irreparable harm, as forecasted in its opening brief. Indeed, Medtronic does not dispute this fact.

Nevertheless, without any support, Medtronic contends that the public-interest prong of the *eBay* test weighs against an injunction, alleging that "evidence submitted by Abbott in support of its Injunction Motion indicates that Endeavor may be associated with fewer dangerous side effects than at least one of the two competing drug-eluting stents." (D.I. 828 at 3.) Medtronic is incorrect. As explained by Dr. Joel Kahn, at the time Abbott filed its opening brief, the safety data that compared the Endeavor to other DES products on the U.S. market, including the data cited by Medtronic, were inconclusive. (*See, e.g.*, D.I. 730 at ¶ 12 ("On the subject of myocardial infarction rates between Endeavor and Cypher, however, the clinical results described in this article were inconclusive").) Since that time, however, further data have confirmed that Medtronic's Endeavor is no safer than the other DES products on the U.S. market

and that the efficacy of the Endeavor is actually inferior to them. As explained in an FDA press release on February 1, 2008, for example, "[t]he number of adverse events experienced by patients implanted with the Endeavor was similar to those that occurred in patients implanted with bare-metal stents and existing drug-eluting stents," while "the Endeavor's restenosis rate was higher than what is seen in currently marketed drug-eluting stents." (Ex. 3 (emphasis added) [FDA Press Release dated Feb. 1, 2008].) Accordingly, the public interest will not be harmed if the Court orders Medtronic to remove the Endeavor from the U.S. market. In fact, the data show that the Endeavor is an inferior product.

4. [redacted]

[redacted]

5. Medtronic's Attempt to Attack *KSM Fastening Systems, Inc. v. H. A. Jones Co.* Is Unavailing

Medtronic argues that "Abbott relies heavily on *KSM Fastening Systems, Inc. v. H. A. Jones Co* , 776 F.2d 1522 (Fed. Cir. 1985)," alleging that this case is no longer good law after *eBay*. (D.I. 828 at 6-7.) Medtronic is incorrect. Abbott cited *KSM* simply to illustrate that the scope of Abbott's proposed injunction—which includes products no more than colorably different from Medtronic's infringing stents and devices that contain or use Medtronic's infringing stents—is consistent with Federal Circuit law. In *KSM*, the Federal Circuit held that "contempt proceedings, civil or criminal, [related to violation of an injunction] are available only with respect to devices previously admitted or adjudged to infringe, and to other devices which are no more than colorably different therefrom and which clearly are infringements of the patent." 776 F. 2d at 1526. Those principles have not been altered by *eBay*. Medtronic's criticism of the *KSM* case has no support and thus should be rejected.

B. Medtronic Should Not Be Permitted to Delay Abbott's Motion for a Permanent Injunction by Taking Discovery on Its Own Product

If the Court grants Abbott's motion to lift the stay on injunction proceedings related to the Endeavor, as an alternate request, Medtronic seeks up to nine months to take discovery concerning the impact that an injunction against the Endeavor might have on the public interest. (D.I. 828 at 3, 8.) Medtronic's alternate request is nothing more than another attempt to further delay resolution of Abbott's injunction motion so that Medtronic can continue infringing Abbott's patents.

While Medtronic asserts that it needs discovery from Abbott concerning its own product—a dubious proposition on its face—Medtronic fails to identify any information related to the Endeavor that it could possibly obtain from Abbott that is not already within Medtronic's possession. Because Medtronic has failed to explain how it could possibly need discovery from Abbott on the Endeavor, or to identify any particular relevant information it believes Abbott could supply, Medtronic's request for discovery should be denied.

Moreover, Medtronic's allegation that it has not taken any discovery related to the DES market in general is incorrect. (D.I. 828 at 3-4.) While Abbott objected to Medtronic's discovery requests relating to the DES market, Abbott nevertheless produced documents that included information related to the DES market (*e.g.*, market share documents). Additionally, Medtronic questioned each of Abbott's witnesses on that subject during their depositions, and Abbott permitted its witnesses to answer those questions. [redacted]

Accordingly, Medtronic already has obtained discovery related to the DES market and should not be given another opportunity to pursue discovery on that same subject.

C. Lifting the Stay on Injunction Proceedings for the Endeavor Need Not Unduly Delay Resolution of Abbott's Injunction Motion

Finally, Medtronic asserts that lifting the stay on injunction proceedings for the Endeavor would unduly delay resolution of this case. (D.I. 828 at 5-6.) Medtronic's argument is based on its improper request for nine months of discovery and its desire to submit additional briefing in opposition to Abbott's injunction motion. Abbott disagrees that lifting the stay on injunction proceedings for the Endeavor would unduly delay resolution of the case. Certainly, it is Abbott, not Medtronic, that seeks to minimize any delay in securing the appropriate remedies (*e.g.*, an injunction and damages) for Medtronic's adjudicated infringement.

As explained above, Medtronic has failed to establish that it should be permitted to take any further discovery from Abbott concerning its Endeavor. Accordingly, the Court should deny Medtronic's request for discovery. Moreover, as far as additional briefing is concerned, if the Court believes that additional briefing on the Endeavor would be helpful, the parties could complete any such supplemental briefing on an expedited schedule. For example, because any further briefing should focus solely on the Endeavor, the Court could permit Medtronic to file a supplemental brief of up to ten pages in length and allow Abbott to file a responsive brief of the same length. This additional briefing could easily be completed within a month (*e.g.*, two weeks for Medtronic to file a supplemental brief and two weeks for Abbott to file a responsive brief).

III. CONCLUSION

For the reasons explained herein and in Abbott's Motion to Lift Stay of Proceedings on Abbott's Motion for Permanent Injunction as to Medtronic's Endeavor, Abbott respectfully requests that the Court grant Abbott's motion and issue an injunction against Medtronic's continuing infringement, including its infringing sales of the Endeavor.

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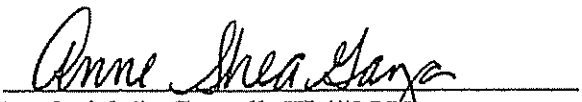
Dated: March 27, 2008



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DISTRICT OF DELAWARE

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